

**What We Claim is:**

1. A polypeptide comprising a sequence selected from SEQ ID No. 2 or SEQ ID No. 4.
2. A polynucleotide that encodes a polypeptide according to claim 1.
3. A polynucleotide according to claim 2, selected from SEQ ID No. 1 or SEQ ID No. 3.
4. A polynucleotide comprising a nucleotide sequence selected from the group consisting of:
  - a) complements of SEQ ID No: 1 or SEQ ID No: 3,
  - b) reverse compliments of SEQ ID No: 1 or SEQ ID No: 3, and
  - c) reverse sequences of SEQ ID No: 1 or SEQ ID No: 3.
5. A polynucleotide comprising a nucleotide sequence that differs from SEQ ID No: 1 or SEQ ID No. 3 as a result of silent substitution(s) or substitution(s) that results in conservative substitution(s) in the resulting amino acid.
6. A polypeptide encoded by a polynucleotide of claim 4 or claim 5.
7. A fusion protein comprising at least one polypeptide according to claim 1 or claim 6 or a fragment thereof.
8. A vector comprising a polynucleotide according to any one of claims 2 to 5.
9. A vector comprising, in the 5'-3'direction:
  - a) a gene promoter sequence;
  - b) a polynucleotide sequence according to any one of claims 2 to 5; and
  - c) a gene termination sequence.
10. The vector according to claim 8 or claim 9, wherein the polynucleotide is in a sense orientation.
11. The vector according to claim 8 or claim 9, wherein the polynucleotide is in an

antisense orientation.

12. A host cell containing a vector according to any one of claims 8 to 11.
- 5 13. A composition for regulating muscle growth, comprising any one of:
- a) a polynucleotide comprising SEQ ID No. 1 or SEQ ID No.3,
  - b) a fragment or variant of (a),
  - c) a polynucleotide having at least 95%, 90% or 70% sequence identity to (a),
  - d) a complement of any one of (a) to (c),
  - 10 e) a reverse complement of any one of (a) to (c),
  - f) an antisense polynucleotide of any one of (a) to (c),
  - g) a polypeptide encoded by any one of (a) to (c),
  - h) a polypeptide comprising SEQ ID No. 2 or SEQ ID No. 4,
  - i) a fragment or variant of (g) or (h), and
  - 15 j) a polypeptide having at least 95%, 90% or 70% sequence identity relating to (g) or (h).
14. A composition for regulating muscle growth, comprising any one of:
- a) a sequence of SEQ ID No. 5,
  - 20 b) a polynucleotide having at least 95%, 90% or 70% sequence identity to SEQ ID No. 5, and
  - c) a fragment or variant of (a) or (b).
15. A composition for modulating mighty gene expression comprising a compound
- 25 capable of binding to a polynucleotide selected from any one of:
- a) SEQ ID No.1, SEQ ID No. 3, or SEQ ID No. 5,
  - b) a polynucleotide that encodes a polypeptide of SEQ ID No. 2 or SEQ ID No. 4,
  - c) a polynucleotide having at least 95%, 90% or 70% sequence identity to (a) or (b),
  - d) a complement of any one of (a) to (c),
  - 30 e) a reverse complement of any one of (a) to (c), and
  - f) a fragment or variant of any one of (a) to (e).
16. The composition according to claim 15 wherein the compound is an anti-sense polynucleotide.
- 35 17. The composition according to claim 15 or claim 16 wherein the compound is an

interfering RNA molecule.

18. The composition according to claim 17 wherein the interfering RNA molecule is an RNAi or siRNA molecule.

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19. The composition according to claim 15, wherein the compound is myostatin.

20. The composition according to claim 15, wherein the compound is a myostatin mimetic.

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21. The composition according to claim 20, wherein the myostatin mimetic is a myostatin peptide C-terminally truncated at or between amino acid positions 330 and 350.

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22. The composition according to claim 20 or claim 21, wherein the myostatin mimetic is a myostatin peptide C-terminally truncated at any one of amino acid positions 330, 335, and 350.

23. The composition according to claim 15, wherein the compound is an antibody.

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24. A composition according to any one of claims 13 to 23 for the treatment or prophylaxis of a disease associated with muscle growth.

25. The composition according to claim 24, wherein the disease is associated with muscle atrophy.

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26. The composition according to claim 24 or claim 25, wherein the disease is selected from muscular dystrophy, muscle cachexia, atrophy, hypertrophy, muscle wasting associated cancer or HIV, amyotrophic lateral sclerosis (ALS), or diseases associated with cardiac muscle growth, including infarct.

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27. A composition according to any one of claims 13 to 23 for promoting muscle regeneration after muscle injury.

28. A method of regulating muscle growth of an organism, comprising administering to said organism a composition according to any one of claims 13 to 23.

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29. The method according to claim 28, for the production of an animal having increased muscle mass.
30. The method according to claim 28, for the treatment or prophylaxis of a disease  
5 associated with muscle growth.
31. The methods according to claim 30, wherein the disease is associated with muscle atrophy.
- 10 32. The method according to claim 30 or claim 31, wherein the disease is selected from muscular dystrophy, muscle cachexia, atrophy, hypertrophy, muscle wasting associated cancer or HIV, amyotrophic lateral sclerosis (ALS), or diseases associated with cardiac muscle growth, including infarct.
- 15 33. A method according to claim 28, for promoting muscle regeneration after muscle injury.
34. The use of a composition according to any one of claims 13 to 23 in the production of a medicament for regulating muscle growth.  
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35. The use of a composition according to any one of claims 13 to 23 in the production of a medicament for the treatment or prophylaxis of a disease associated with muscle growth.
- 25 36. The use according to claim 35, wherein the disease is associated with muscle atrophy.
37. The use according to claim 35 or claim 36, wherein the disease is selected from muscular dystrophy, muscle cachexia, atrophy, hypertrophy, muscle wasting associated  
30 cancer or HIV, amyotrophic lateral sclerosis (ALS), or diseases associated with cardiac muscle growth, including infarct.
38. A use of a composition according to any one of claims 13 to 23 in the production of a medicament for promoting muscle regeneration after muscle injury.  
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39. A transgenic animal comprising a vector according to any one of claims 8 to 11, or

a composition according to any one of claims 13 to 18.

40. The transgenic animal according to claim 39, wherein said animal has an increased muscle mass.

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41. The transgenic animal according to claim 39 or claim 40, selected from a sheep, cow, bull, deer, poultry, turkey, pig, horse, mouse, rat or human.

42. A method of predicting muscle mass in an animal, comprising the steps of:

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i) obtaining a sample from the animal,

iii) determining the gene expression level from a polynucleotide having a sequence of SEQ ID No.1 or SEQ ID No.3, a polynucleotide having at least 95%, 90% or 70% sequence identity to SEQ ID No. 1 or SEQ ID No.3, or a fragment or variant thereof; or determining the amount of a polypeptide

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having a sequence of SEQ ID No.2 or SEQ ID No.4, a polypeptide having at least 95%, 90% or 70% sequence identity to SEQ ID No. 2 or SEQ ID No.4, or a fragment or variant thereof,

iv) comparing the gene expression level or amount of polypeptide to an average; and

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v) predicting the muscle mass of said animal.

43. The method according to claim 42, wherein the level of gene expression is determined using RTPCR or northern analysis.

25 44. The method according to claim 43, wherein the amount of the polypeptide is determined using ELISA or Western blot analysis.

45. A method of detecting a variant of mighty, comprising the use of a nucleotide sequence selected from:

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a) SEQ ID No.1, SEQ ID No. 3, or SEQ ID No. 5,

b) a polynucleotide that encodes a polypeptide of SEQ ID No. 2 or SEQ ID No. 4,

c) a polynucleotide having at least 95%, 90% or 70% sequence identity to (a) or (b),

d) a complement of any one of (a) to (c),

e) a reverse complement of any one of (a) to (c), and

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f) a fragment or variant of any one of (a) to (e),

to screen a sample from an organism for the variant of mighty.

46. The method according to claim 45, wherein the variant is a polymorphism.
47. The method according to claim 46, wherein the polymorphism is a single  
5 nucleotide polymorphism.
48. The method according to any one of claims 45 to 47, wherein the variant of mightly is associated with an altered muscle phenotype.
- 10 49. A method of breeding an animal having improved muscle mass comprising the steps of:
- i) selecting one or more animals predicted to have an increase in muscle mass using the method according to any one of claims 42 to 44 or 48, and
  - ii) breeding the one or more animals predicted to have an increased muscle  
15 mass to produce an animal having an improved muscle mass.
50. The method according to claim 49, wherein the animal is selected from a sheep, cow, bull, deer, poultry, turkey, pig, horse, mouse, rat, fish or human.
- 20 51. An antibody that preferentially binds a polypeptide having a sequence of SEQ ID NO. 2 or SEQ ID NO. 4 or a polypeptide having at least 95%, 90% or 70% sequence identity to SEQ ID NO. 2 or SEQ ID NO. 4.
52. An antigenic fragment of a polypeptide comprising a sequence of SEQ ID NO. 2 or  
25 SEQ ID NO. 4 in the production of an antibody that preferentially binds a sequence of SEQ ID NO. 2 or SEQ ID NO. 4 or a polypeptide having at least 95%, 90% or 70% sequence identity to SEQ ID NO. 2 or SEQ ID NO. 4.
53. An isolated polynucleotide comprising any one of:
- 30 a) a sequence of SEQ ID No: 5,
  - b) a polynucleotide having at least 95%, 90% or 70% sequence identity to SEQ ID No. 5, and
  - c) a fragment or variant thereof having promoter activity.
- 35 55. An isolated polynucleotide according to claim 54, comprising at least the 200 nucleotides upstream of the mighty initiation site.

56. An isolated polynucleotide according to claims 54 or claim 55, comprising fragments of any one of 209, 287, 315, 400, 600, 1000 and 2100 nucleotides upstream of the mighty initiation site.
57. A vector comprising a polynucleotide according to any one of claims 54 to 56.
58. A host cell containing a vector according to claim 57
59. A method of screening for one or more compounds that are potentially useful in inhibiting or promoting muscle growth, comprising the steps of:
- i) inserting a polynucleotide according to any one of claims 54 to 56 into a suitable vector linked to a suitable marker gene;
  - ii) transforming a suitable host cell with the vector;
  - 15 iii) administering a compound of interest to the host cell; and
  - iv) determining any difference in the level of the marker gene expression.
60. The method according to claim 59, wherein the vector is any one of a prokaryotic plasmid, a eukaryotic plasmid or a viral vector.
- 20 61. The method according to claim 59 or claim 60, wherein the marker gene is any one of a polynucleotide that encodes any one of: a green fluorescent protein, a red fluorescent protein, a luciferase enzyme, or a  $\beta$ -galactosidase enzyme.
- 25 62. A method of expressing a desired protein in a muscle cell, comprising the steps of:
- i) isolating a polynucleotide sequence that encodes the gene to be expressed;
  - ii) inserting a polynucleotide according to any one of claims 54 to 56, operably linked to the polynucleotide sequence of the protein to be expressed in a 5' – 3' orientation, into a suitable vector, and
  - 30 iii) introducing the vector into a muscle host cell.
63. The method according to claim 62, wherein the vector is any one of a eukaryotic vector, viral vector, or any vector suitable for gene therapy.
- 35 64. The method according to claim 62 or claim 63, wherein the host cell is any one of a primary myoblast cell line, a transformed myoblast cell line or any cell line in which the

mighty promoter is active.

65 The method according to claim 62 or claim 63, wherein the host cell is an *in vivo* skeletal or cardiac muscle cell of a host animal.

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66. The method according to claim 65, wherein the host animal is any one of a sheep, cow, deer, bull, poultry, turkey, pig, horse, mouse, rat, fish or human.